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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,118

06/11/2007

Prakash Singh Bisen

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,118	<b>Applicant(s)</b> BISEN ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 6 February 2009, is acknowledged.

Claims 11, 15, 17, 18 and 21 have been amended. New claims 22-25 have been added.

2. Claims 11-25 are pending and under consideration.

### **Rejections/Objections Withdrawn**

3. The objection to claim 17 is withdrawn in light of the amendment of the claim.

4. The rejection of claims 11, 12, 13 and 14 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of "antigen", is withdrawn in light of the amendment of the claims.

5. The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for "the lipid", is withdrawn in light of the amendment of the claim.

6. The rejection of claims 15-21 under 35 U.S.C. 112, second paragraph, as being indefinite for "dark blue dye", is withdrawn in light of the amendment of the claims.

### **Rejections Maintained**

7. The rejection of claims 15, 16 and 18-21 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of "antigen", is maintained for reasons of record.

Applicants argue that the amendment of the claims obviates the rejection.

The examiner has considered applicants argument in light of the claim amendments, but does not find it persuasive.

Newly amended claim 15 is now drawn to a method comprising the steps of applying a positive control, a negative control and a sample to a hydrophobic material, adding antigen suspension to said positive, said negative and said sample, and interpreting a result, wherein clumping of a specific antigen in the suspension and an antibody in the positive control and the test sample is prognostic for an active tuberculosis infection. The added terminology further

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describes the controls, not the antigen suspension being used. Thus, it remains unclear what is the antigen.

Claim 16 merely states that the antigen suspension is a liposome antigen and does not clarify the source of the antigen.

Claims 18-21 merely recite how the antigen suspension is obtained and does not clarify the source of the antigen.

### **Claim Rejections - 35 USC § 112**

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 17 and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from claim 15 which is now drawn to a method comprising the steps of applying a positive control, a negative control and a sample to a hydrophobic material, adding antigen suspension to said positive, said negative and said sample, and interpreting a result, wherein clumping of a specific antigen in the suspension and an antibody in the positive control and the test sample is prognostic for an active tuberculosis infection. The added terminology to claim 15 describes further the controls, not the antigen suspension being used. Thus, it is unclear what is the antigen.

As newly amended, claim 17 merely recites how the positive control is obtained and does not clarify the source of the antigen utilized in the method of claim 15.

Claims 22-25 are dependent from claim 15, but do not clarify the identity of the antigen utilized in the claimed method. Claims 22-25 merely recite the reactivity of the antibodies

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utilized in the controls. Therefore, it is unclear how the method can function for detecting tuberculosis if none of the listed antigenic components are tuberculosis antigens.

10. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is dependent from claim 16 which is dependent from claim 15. As newly amended, claim 17 is now directed to a method, wherein said positive control is prepared comprising the steps leading to purifying a lipid composition.

The positive control of claims 15 and 16 is "an anti-mycobacterial glycolipid antibody". Thus, it is unclear what claim 17 is claiming because it recites that the positive control is prepared by purifying a lipid composition only. There is no recitation of antibody production.

### **Conclusion**

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 24, 2009